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I, LEANNE MYNOTT, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. PP 5732 for a patent by WOLFE RESEARCH PTY LTD filed on 04 September 1998.

WITNESS my hand this
Eleventh day of October 1999

L. Mynott

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SUPPORT AND SALES

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Regulation 3.2

Wolfe Research Pty Ltd

A U S T R A L I A

Patents Act 1990

PROVISIONAL SPECIFICATION

for the invention entitled:

"Implantable Wireless Stimulator and Stimulation Feedback System"

The invention is described in the following statement:

IMPLANTABLE WIRELESS STIMULATOR AND STIMULATION FEEDBACK SYSTEM

This invention relates to a wireless receiver and muscle activation device which is suitable for surgical implant, and a feedback system which can be used in conjunction with the muscle stimulator.

Normal and healthy individuals are able to contract their muscles in order to interact functionally with the environment. However, a number of people all over the world lose their natural ability to control their muscle contraction and are thus physically disabled. Functional Electrical Stimulation (FES) is a technique which incorporates the stimulation of muscles for providing functionality to people suffering from neuromotor control disorders or have otherwise lost their natural ability to control and contract their muscles usefully. The disorder or loss of natural ability can arise through a range of causes, including disease, trauma or stroke.

FES devices can be classified into two categories - implants and external. External FES devices include some simple devices such as those used to correct drop foot, and have been in use for a few decades. The implantable devices are relatively new and the first commercialisation of such a device took place in 1997. The implantable devices currently used consist of a controller and a set of electrodes all of which are hardwired and the wires run inside the body (Memberg, Peckham, Keith, "A Surgically Implant Intramuscular Electrode for An Implantable Neuromuscular Stimulation System", IEEE trans.Rehab.Eng., vol. 2, no.2, Jun 1994). The commercially available devices provide up to 16 stimulating electrodes. The prior art device does not have any power source and it is powered by a magnetic field coupling (e.g. in the form of a coupling between primary and secondary transformer windings) which provides power from a controller which is outside the body.

Devices have been reported which provide the same function but are wireless (US Patent No. 5,358,514 to Schulman et al; Matjacic et al "Wireless Control of Functional Electrical

Stimulation Systems", PMID:9148704, UI:97205715; Sawan, Hassouna et al "Stimulator Design and Subsequent Stimulation Parameter Optimization for Controlling Micturition and Reducing Urethral Resistance", IEEE trans. Rehab.Eng., vol.4, no.1, Mar 1996). In these devices, each of the electrodes (devices) is addressable. The power is received using the coupling of an oscillating magnetic field between the transmitter and the receiving electrode. The devices reported have employed frequencies of the magnetic field between 400 K Hz to 50 M Hz.

In all these devices, a major drawback is that the receiver has to be within the oscillating electromagnetic field of the controller. This is extremely restrictive because it suggests that the source has to be in the close proximity of the muscles to be stimulated. Also, at these frequencies, absorption by the tissues is high and there could be some unwanted and undesirable effects to the body.

Furthermore, in healthy subjects the ability to control muscle contraction is achieved by forward commands based on the Central Neural System activity and feedback information from the body sensors and memory based intelligent decisions made in the Peripheral Neural System. For patients who have lost their natural ability to control muscle contraction, modern technology provides a means of stimulating the muscles of such people, such as the above discussed Functional Electrical Stimulation (FES) techniques. The FES systems reported in the prior art provide the forward loop control for the muscles. Devices have been designed which record information from the extremities - either by recording neural activity or by using sensors (like pressure or vibration etc) and feedback this information to the subject (Haugland, Hoffer et al "Skin Contact Force Information in Sensory Nerve Signals Recorded by Implanted Cuff Electrodes", IEEE trans.Rehab.Eng.,vol.2, no.1, Mar 1994). Some difficulties associated with these techniques are that the information is unnatural and the subjects have to learn to react to this information, and the invasive nature of their implementation.

Available devices like the drop foot FES system automatically restore the gait of the subject

and are not under the conscious control of the subject. FES systems like grasp control devices and other similar systems work under the linear control of the subject. These latter devices have a number of drawbacks which are summarised below:

1. Total visual attention of the subject is required. This makes the application of the device extremely restrictive.

2. These devices are not intelligent. Unlike the body which has a Peripheral Neuromotor control mechanism which works along with the Central Neural System (CNS), subjects fitted with the FES devices have to use their CNS to monitor and control the muscle contraction.

A number of researchers have proposed systems which provide feedback to the subjects (Haughland, Hoffer et al, "Skin Contact Force Information in Sensory Nerve Signals Recorded by Implanted Cuff Electrodes", IEEE trans.Rehab.Eng. vol.2, no.1, Mar 1994; Hoffer JD, "Closed Loop, Implanted Sensor, Functional Electrical Stimulation System for Partial Restoration of Motor Functions", US Patent No. 4,750,499]. These systems primarily utilise invasive methods like recording the neural activity from the nerves, embedding sensors inside the body or fixing them on the surface of the body. These techniques are highly invasive and also restrictive to the subjects. Information being fed back to the subject is not definitive in case of neural implants, and in case of recordings from sensors the feedback is not natural.

In accordance with one aspect of the present invention, there is provided a stimulation device for providing *in vivo* artificial electrical stimulation, comprising a receiver antenna for receiving electromagnetic radiation from a transmitted source, a supply circuit for deriving electrical energy from the received electromagnetic radiation, an isolating circuit for isolating data signals from the received electromagnetic radiation, a pulse generator for generating electrical pulses according to the data signals utilising the electrical energy from the supply circuit, and a stimulating electrode for outputting the electrical pulses from the pulse generator.

In other words, the stimulation device of the present invention comprises an antenna for receiving electromagnetic radiation from a controlled source and converting it to an oscillating current, a converter for converting the oscillating current to an electrical supply suitable to provide power for the device, an isolating circuit for separating a data signal from the oscillating current, and a pulse generator activated according to the data signal to provide electrical stimulation pulses using said electrical supply power.

Preferably the stimulation device is constructed to be implanted within the tissue of a living subject, for example to stimulate and control muscle contraction by way of the output electrical pulses. The stimulation device may therefore be at least substantially encapsulated in a biocompatible material, such as a suitable epoxy or the like. The stimulating electrode can be constructed from a suitable biocompatible conductive material, such as titanium. It is preferred that the components of the stimulation device be contained in a single substantially encapsulated unit for ease of surgical implantation, however it is possible that the antenna and/or electrode be separate and connected to the remainder of the device by way of a short wire, for example. This construction may be desirable where the site to be stimulated by the device (i.e. the desired position of the electrode) is located relatively deep within the subject tissue, but it is nevertheless desirable for the antenna to be near the tissue surface for reduced attenuation of the electromagnetic radiation received at the antenna. It may additionally be desirable to provide a coating or patch of an antireflection material on the tissue surface over the antenna to further reduce electromagnetic radiation signal attenuation. The preferred range of electromagnetic radiation frequencies for conveying the power and carrying the control signals from the transmitter/controller to the receiver/activator is about 2 GHz to about 40 GHz.

In a particular application of the invention it is desirable for a plurality of stimulation devices to be responsive to signals from a common transmission source. In this case it is desirable for each stimulation device, or groups of stimulation devices, to be selectively actuable by the received data signals. Accordingly, the isolating circuit or pulse generator is preferably constructed to be addressable by certain data signals, such that stimulation pulses are only

generated if a certain form of data signal is received from the transmission source. For example, the stimulation device can be constructed to decode modulated digital codes and compared with predetermined codes to ascertain whether that particular device is being addressed. Alternatively, a form of frequency signal coding can be used, and the isolating circuit adapted to isolate only the data signals intended for that device. Other data encoded in the data signals can be utilised by the pulse generator to control the characteristics of electrical pulses generated, such as pulse shape, magnitude, duration and frequency.

In accordance with another aspect of the invention, there is provided an artificial muscle stimulation system comprising at least one stimulating electrode for providing artificial electrical stimulation to a muscle *in vivo* under control of an external controller, an electromyographic (EMG) sensor for measuring EMG signals from the muscle during stimulation, a neural network processor coupled to receive the measured EMG signals to extract information regarding force of contraction and fatigue of the muscle, and wherein the external controller is coupled to an output of the neural network processor to control said artificial electrical stimulation based on said extracted information.

The invention is described in greater detail hereinbelow, by way of example only, with reference to the accompanying drawings, wherein:

Figure 1 is functional block diagram of a wireless electrical muscle stimulation system according to an embodiment of the present invention;

Figure 2 is a functional block diagram of a receiver and activator for a wireless FES system;

Figure 3 is a block diagram of an alternative form of the invention;

Figure 4 is a block diagram showing the construction of a digital form of the receiver activator; and

Figure 5 is a block diagram of a system for providing feedback for artificial stimulation.

A receiver and addressable activating device to enable electrical stimulation of muscles

(skeletal, smooth or cardiac) is described below. This receiver is constructed to enable it to be implantable within the body of the subject, and in practice a plurality of receivers would be implanted at different locations in the body to stimulate different muscles. The receiver is also constructed to enable it to operate without requiring an in-built energy source. The receiver derives its energy for operation from electromagnetic radiation emanating from a transmitter. The transmitter also provides, by way of the electromagnetic signals, control commands to control the receiver and activator so as to produce appropriate electrical stimulation signals to the muscle.

To enable a wireless FES system utilising the present invention to operate with multiple receivers/activators stimulating different muscles and controlled by a single transmitter, it must be possible to control each receiver/activator individually. To achieve this, each receiver can be constructed to respond only to a certain form of signal issued from the transmitter. There are various ways in which that can be implemented, including a digital addressing scheme and a frequency coded addressing scheme. Because the system is wireless, and both power and control signals are transmitted from the controller to the multiple receivers by way of electromagnetic radiation, numerous receiver/activators can be controlled using a single transmitter without the difficulties associated with implanted or even external wiring, such as wires passing through jointed areas in the body.

Each receiver includes an antenna, also implanted, tuned to receive the electromagnetic radiation from a transmitter which may be worn on or about the body of the subject. The high frequency RF (or near optical) electromagnetic signals are preferably in the range of 2 to 40 GHZ. A portion of the signal energy is utilised to provide electrical power to the activator circuitry, and another portion of the signal is decoded to provide control information such as the address of the receiver/activator and the shape and size of pulse to be provided at the output electrode.

This receiver/activator device is preferably encapsulated using a biocompatible epoxy. The output of the activator is a stimulating electrode which is preferably constructed of titanium

or a similar biocompatible conductive material. The electrodes are self attaching or saturable to the muscle, and can be constructed of a form which are known in the art. The size of each output electrode may be of the order of 4 mm to 20 mm in diameter and a thickness of 3 mm ±1 mm. To implant the device, a local insertion has to be made. If the muscle to be stimulated is located relatively deep inside the body, the receiving portion of the device, including the antenna, can be located near the surface and provided with a short wire link to the activating site. The end of the wire can be, for example, a hook electrode to provide the muscle stimulation. It may be advantageous to provide a coating or patch of an antireflection material (suitable for the electromagnetic frequency utilised for communication between the transmitter and receiver) positioned on the skin of the subject where the receiver is located, if it is desirable to reduce the required level of radiated energy such as for the abdomen area.

Figure 1 is a functional block diagram of a transmitter and receiver system according to one form of the invention. The receiver and activator device 10 is also illustrated in block diagram form in Figure 2. The device 10 includes a dipole antenna 12 which is constructed to receive electromagnetic signals radiated from the transmitter 2. Data signals and power is transmitted by the transmitter at frequencies which are preferably in the range of 2 to 40 GHz. The dipole antenna 12 can be constructed from a suitable conductive material, such as titanium, on an integrated circuit die, and may have the dimensions of, for example, 8 mm length, 4 mm width and 2 mm depth. The signals received by the antenna are passed to passive demodulating circuitry 14 of known construction. Signals of one frequency, F_1, are thereby demodulated to provide an electrical power source Vbias for the activating circuitry 22, 24, 26. The electrical power provided by the output of demodulator 14 is used to charge the capacitive storage element 16. At the preferred frequencies, the absorption of electromagnetic radiation by the body tissues is low, and thus undesirable effects are reduced as compared with the prior art inductive coupling systems mentioned hereinabove.

A second frequency, F_2, produced by the transmitter is the carrier frequency which carries information responsible for addressing and controlling the specific receiver/activator device 10. Passive filtering circuitry 18 of conventional design can be used to isolate the control

signals at carrier frequency F_2, which are then demodulated. The control signals provided by the output of the demodulator 20 are passed to the activator circuitry 22, 24, 26, which is described in greater detail hereinbelow.

In this particular form of the invention, it is envisaged that there are two primary options for receiving the data or activation commands: 1) using RF electromagnetic signals, or 2) using near optical signals. In the case where the data is received using RF, the receiver antenna receives the address and activation command by a digitally coded burst of RF electromagnetic signals at a carrier frequency which is different from F_1, the carrier of the energy. Demodulation of this RF electromagnetic burst provides the digitally encoded information. The other option employs near optical wavelength signals where the data is coded by an ON/OFF technique. The optically sensitive receivers provide a digital stream which is similar to the stream received by demodulating the RF burst. The data so received in the digital stream consists of the address, activation command and the information regarding the shape and size of the pulse to be output by the stimulation electrode. The coding of the information can be achieved in two parts, for example the address followed by the activation pulse details.

The activation circuitry portion of the device 10 includes of a digital register and comparator 22 which is able to decode the address portion of the transmitted data. The address is provided to enable selection of one single activation device or a group of devices, and a given activator may be required to be able to decode more than one address (e.g. one address for the particular device itself, and one address for each of group of devices it may belong to). The second burst of pulses is decoded by the devices selected according to the address information, and this provides the information for that device regarding the shape and size of the pulse to be generated at the stimulating electrode. The pulse according to the received data is thus generated by the pulse generator 24, which can also be of conventional form, appears at the electrode plate 26 to stimulate the tissue it is embedded in. The electrode plate may be physically next to the rest of the receiver/activator device 10, or may be a short distance away and coupled thereto by an insulated multistrand SS wire, for example.

The device 10 is designed to deliver a variable current from the output electrode 26. This provides the flexibility for use in various different applications. The shape and rate of the train of pulses generated by the pulse generator is dependent on the transmitted signals, and can be dynamically controlled by the external controller to meet the muscle recruitment requirements. This flexibility is useful in order to be able to have a control over the recruitment of motor units. This is a feature that the existing stimulators have not been able to offer.

A variation of the invention is illustrated in block diagram form in Figure 3, in which the appropriate activating device is addressed by a choice of modulating tones which is decoded by means of band pass filters 28. In this case, the duration of the tone can be used to determine the width of the pulse to be output by the pulse generator 24. The pulse then appears at the electrode plate 26 and drives a current stimulus through the tissues it is embedded in. Once again, the electrode plate may be physically next to the remainder of the activator device or may be a short distance away and coupled thereto by an insulated multistrand SS wire, for example. It is of course preferable for the electrode to be a close as possible to the activator in order to minimise any electrical losses in conveying the stimulating pulse signals to the electrode.

Figure 4 illustrates in block diagram form a digital implementation of the receiver/activator 30, in which the functions of the signal filtering, demodulation, address decoding and pulse generation are all performed by a single integrated microprocessor and A/D converter circuit 34. The power for the circuit 34 is provided by the power supply circuit 32, which operates in the same manner as described hereinabove, deriving usable electrical current from the electromagnetic radiation received at the receiver antenna 12. The functions of the microprocessor and A/D converter circuit are controlled by, for example, micro-coded computer program instructions in a known way. The stimulations pulses to the electrodes 26 are driven directly from the integrated circuit, and this diagram also illustrates the possibility of driving more than one electrode from a single receiver.

Features of the device described herein include the simple construction which makes it robust and immune to the traumatic environment existing inside the body. There are no coils in the device since inductive coupling is avoided. There are no chemical reactions which may occur in devices which have charge storage bimetallic capacitors. Lengthy wires are not required, which makes the surgical implantation procedures very simple. The device characteristics do not change if there is tissue growth, and a controllable pulse duration and stimulating current is provided for. This is useful in case where the muscle characteristics were to change - whether over a long duration of time (e.g. through aging) or over a short duration (such as through muscle fatigue).

Because the stimulator devices of the present invention do not require wired connections from the controller, numerous stimulator devices can be implanted without the difficulties associated with the wires bypassing joints in the subject. For example, it is estimated that a minimum of perhaps 50 separate artificial stimulators would be required to restore a walking function in a subject with disabled motor functions to the legs, and wires to that many stimulator sites would be very problematic. The present invention can, however, easily accommodate that number of receiver/activators, with each individually addressable or addressable in selected groups. For example, with addressing of the receivers by respective digital codes, an eight bit code would enable selective activation of 256 devices and/or groups of devices.

In conjunction with FES stimulation, an aspect of the present invention also encompasses a system which includes an EMG recorder, an intelligent signal processor and an artificial stimulation controller. The purpose of the overall system is to be able to control the muscle stimulation pattern in order to provide near natural muscle contraction for subjects with neuromotor control disorder. An embodiment of this aspect of the invention incorporates the following features:

1. The system uses EMG measurements from the muscles under stimulation to provide feedback for controlling the artificial stimulation.

2. The system processes the EMG using neural network processing to extract information relating to muscle fatigue.

3. The system can also process the EMG using the neural network processing to extract information relating to force of contraction of the muscle under consideration.

4. The system is then able to control the muscle stimulation based on the muscle fatigue status and the net force of contraction being produced by the muscle.

The above features can be implemented in the following manner:

1. Neural Networks and Time frequency atoms have been used in past to analyse EMG (Englehart K et al, "Classification of Myoelectric Signal Burst Patterns Using A Dynamic Neural Network", IEEE 1995; Hiraiwa A et al, Shimohara K and Tokunga Y, "EMG Pattern Analysis and Classification by Neural Network" IEEE 1989; Jang GC, Cheng FHY, Lai JS and Kuo TS "Using Time Frequency Analysis Technique in the Classification of Surface Emg Signals", IEEE 1994). The present system utilises similar techniques to analyse EMG of the FES stimulated muscles for the purpose of having a closed loop FES system.

During a training phase which is performed under supervision, a fixed stimulation pattern is applied to different electrodes in the same muscle. EMG recordings are memorised by the neural network against the muscle contraction pattern. The system learns the correlation of the EMG signal, force and fatigue. Fatigue is also taught to a parallel system with the help of the spectrum of the signal.

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2. During the training period, the system stimulates the same muscle with the help of different pulse shapes and amplitudes and records the force of contraction. The system is self learning and this can continue even when the stimulating device is implanted.

3. The system incorporates nested neural networks. The network learns the correlation between time, wave shape and strength of contraction.

4. The trained system receives the EMG signal from the muscles being stimulated. The system works in a closed loop and with the help of training, it correlates time EMG wave shape and spectrum with force of contraction and fatigue. The system then changes the pulse shape and rate of muscle stimulation in order to achieve a constant muscle contraction. The system is thus able to predict and compensate for the muscle fatigue. By suitably selecting a various different sets of electrodes in the same muscle, motor recruitment can therefore be altered and muscle fatigue prevented or reduced.

An example of an implementation of such as system 40 is illustrated in block diagram form in Figure 5. In the system 40 a stimulation controller 42 is used to artificially stimulate the subject's muscle 54 by way of FES electrodes 52 in order to achieve muscle contraction in the subject. EMG sensors 48 measure EMG feedback signals from the muscle, which are passed to an analyser circuit 46 and thence to a neural network processor 44. The neural network processor 44 provides electrical feedback to the stimulation controller 42 according to discerned muscle fatigue, etc. A joystick 50 or the like, under control of the subject, can provide physical feedback signals indicative of, for example, muscle contraction force.

The above described system thus enables a technique for processing surface EMG using intelligent signal processing techniques incorporating Neural Networks. The technique extracts information related to the status of muscle fatigue and force of the stimulated muscle. The system can therefore provide information related to change in motor recruitment and stimulation in order to maintain constant force of contraction and prevent fatigue. It can also analyse the need by the subject to increase or decrease the force of contraction of any muscle. This information may be used to directly control the stimulation rate and electrode address based on which the FES system is controlled.

The foregoing detailed description of the present invention has been presented by way of example only, and is not intended to be considered limiting to the invention, which includes, individually and collectively, every novel feature and combination of novel features herein disclosed.

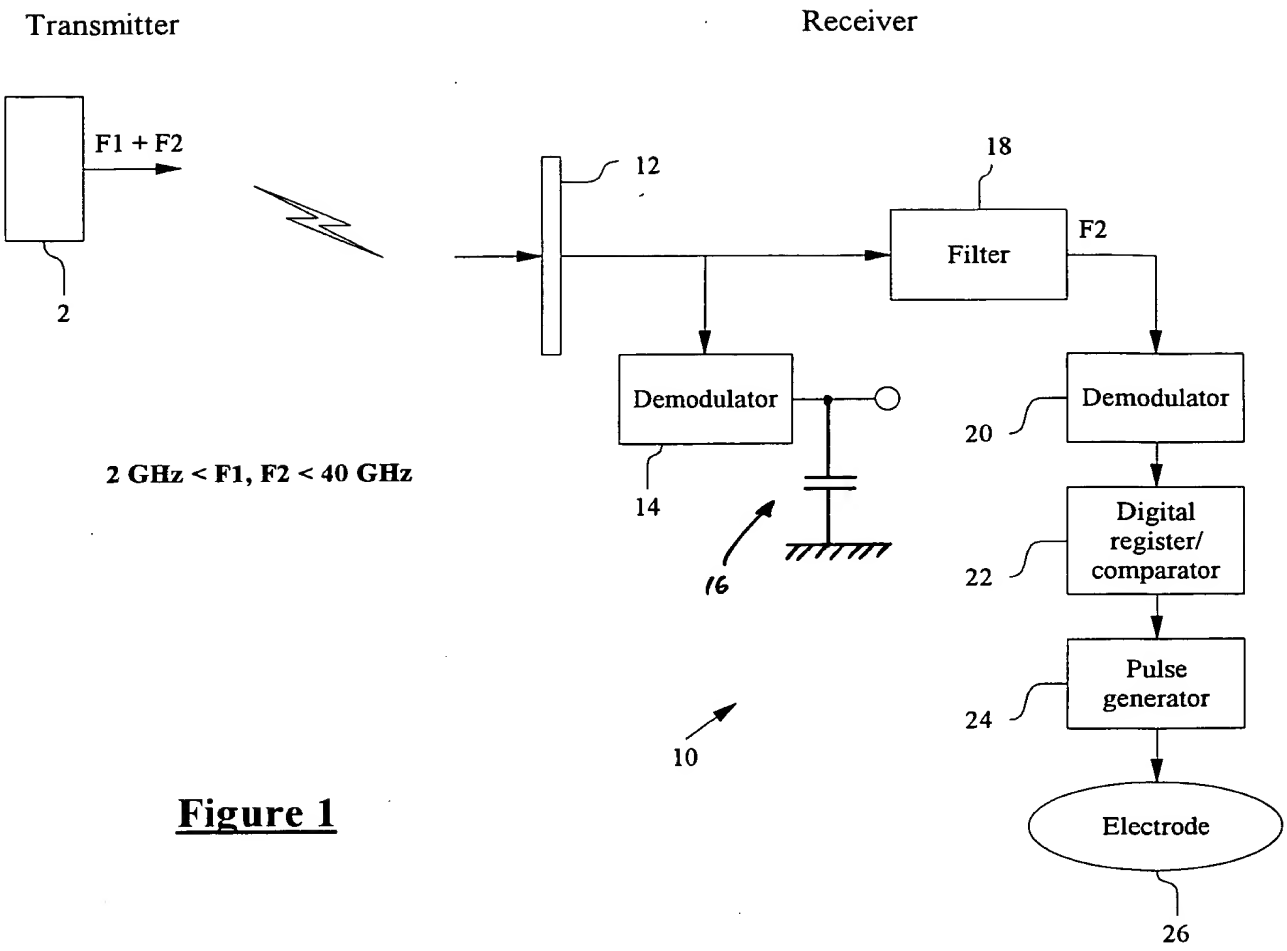

Figure 1

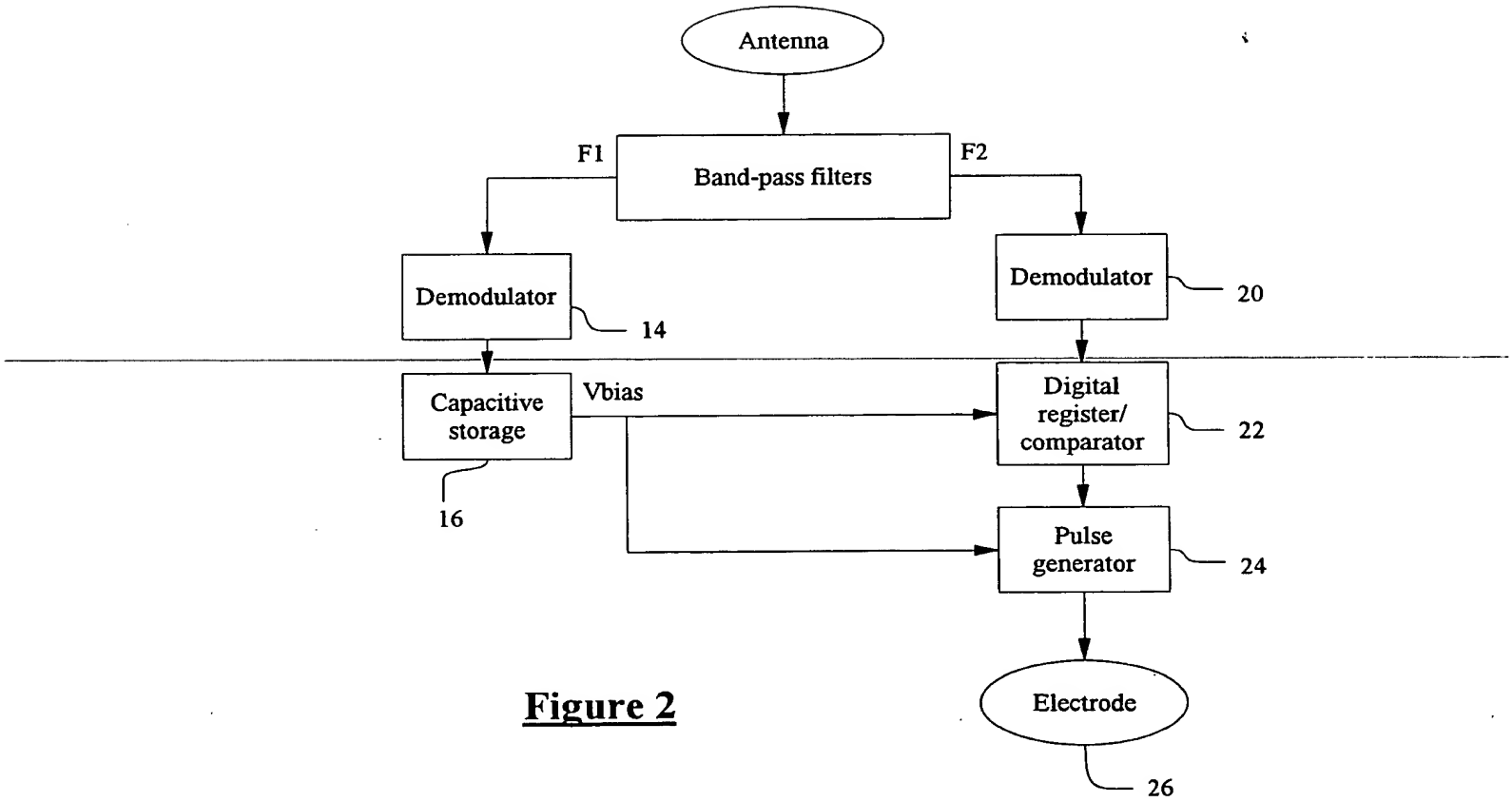

Figure 2

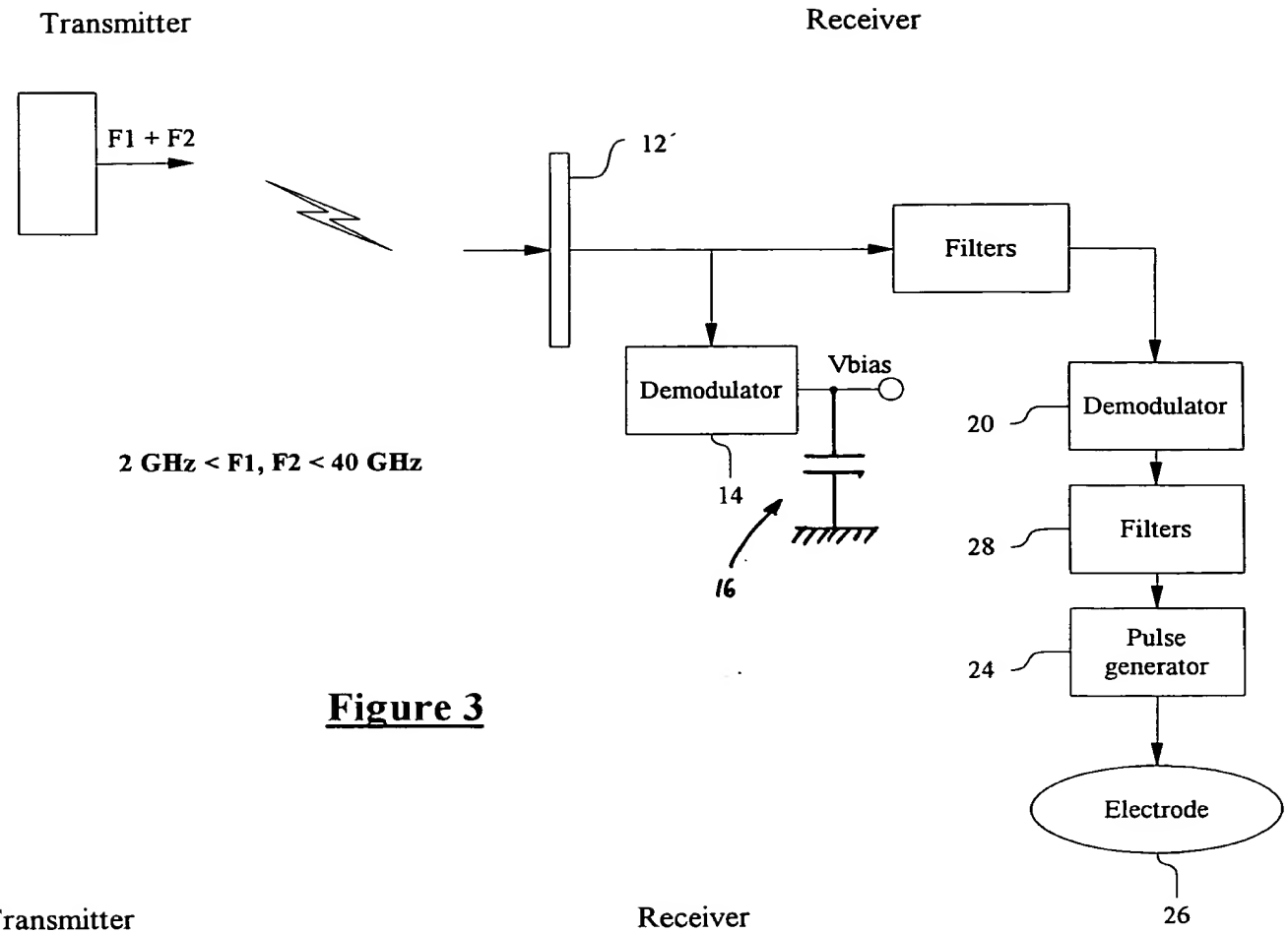

Figure 3

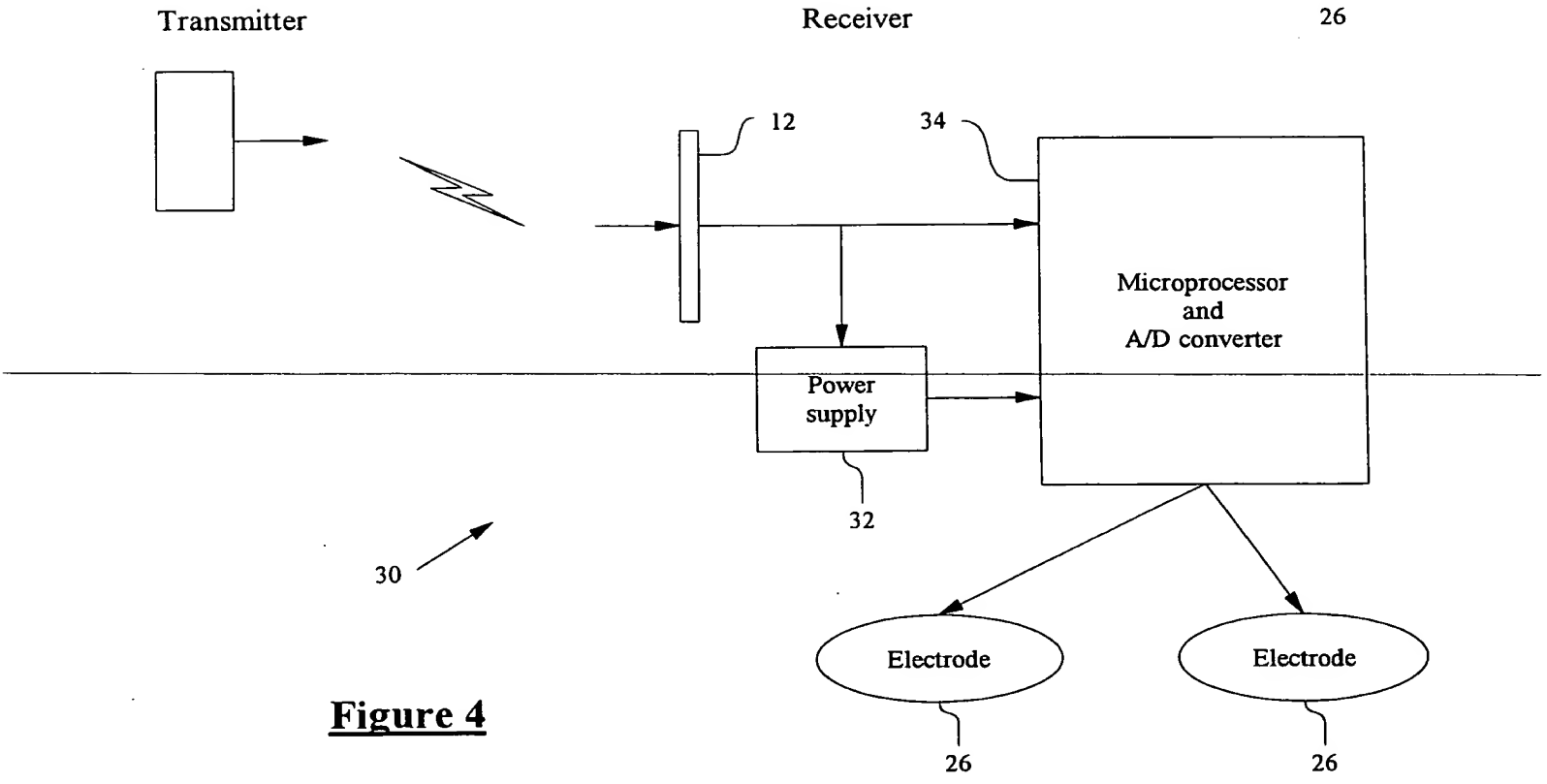

Figure 4

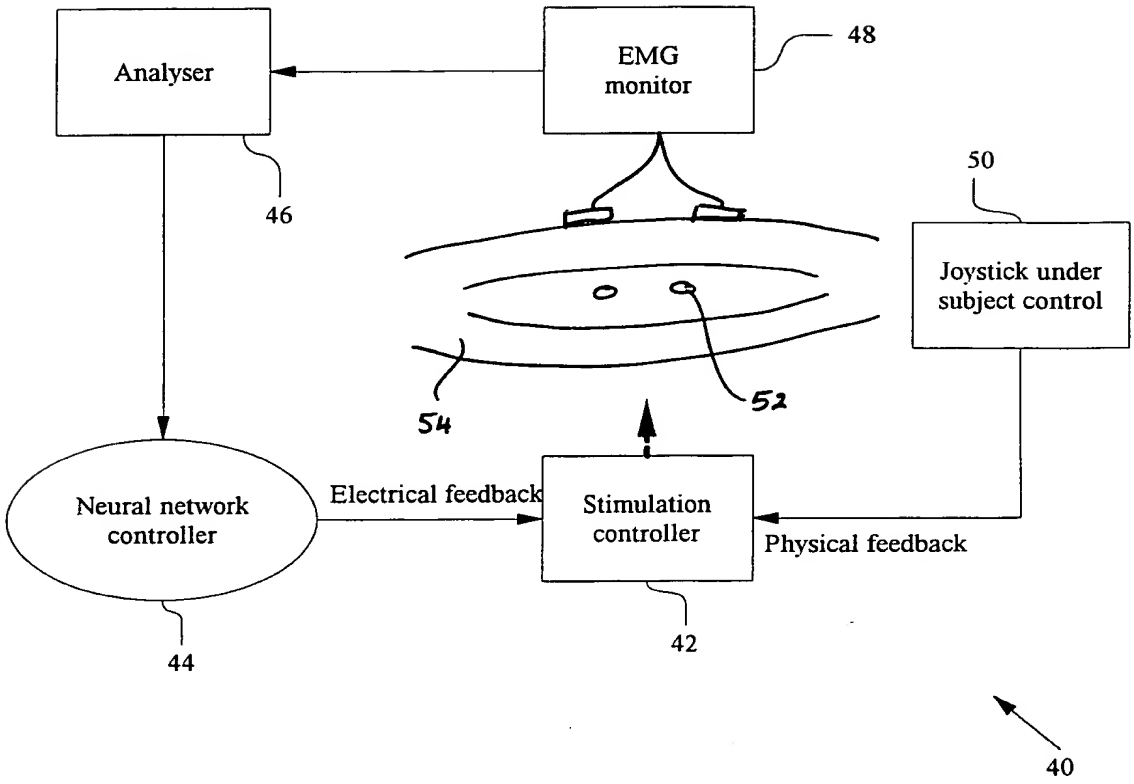
Analyser
EMG monitor
48
46
50
Joystick under subject control
54
52
Neural network controller
Electrical feedback
Stimulation controller
Physical feedback
44
42
40

Figure 5